DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1599]

Agency Information Collection Activities; Proposed Collection; Comment Request; Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recordkeeping requirements to insure public health and safety for manufacturers of impact-resistant lenses used in eyeglasses and sunglasses.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written or electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses (OMB Control Number 0910–0182)—Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)), every manufacturer or importer of a device intended for human use shall establish and maintain records. This regulation is designed to protect the eyeglass and sunglass wearer from potential eye injury resulting from shattering of ordinary eyeglass lenses, and it requires that eyeglasses and sunglasses be fitted with impact-resistant lenses. Section 801.410(f) (21 CFR 801.410(f)) requires that the results of impact tests and description of the test method and apparatus also be

kept for a period of 3 years. These records are valuable to FDA when investigating eye injury complaints

The expected respondents to this collection are manufacturers of impact-resistant lenses. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.410(f)	30	769,000	23,070,00	.0008	18,456

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The Vision Council of America (www.visionsite.org) provided sales figures that were used in estimating the burden for this collection. Beginning in 1998, a growth rate of 2.6 percent for the distribution of lenses began, and it was assumed that this growth rate continued in 1999 and 2000. This resulted in an increase in the number of eyeglasses shipped annually to 89 million lenses shipped by year 2000.

By also assuming that the glass/plastic lenses-produced ratio remained as in previous years (22 percent glass and 78 percent plastic), that glass lenses must be tested individually, and only 5 percent of the plastic lenses must be tested, then 23,070,000 lenses should be tested. This figure was derived by taking 22 percent of 89 million glass lenses (19,600,000) and adding it to 5 percent of the remaining plastic lenses (5 percent x 69,400,000 = 3,470,000).

Next, divide the total tests (23,070,000) by 30 manufacturers to return the annual frequency of recordkeeping figure of 769,000. Previously, FDA and industry experts estimated that on average, each test could be completed and recorded in 3 seconds. Industry, therefore, could complete 1,200 tests per hour. Therefore, it is estimated that the total burden for this collection is 19,225 hours, which is calculated by taking the total records figure (23,070,000) and dividing it by tests per hour (1,200). The total hours was calculated by multiplying the total number of records (23,070,000) and the hours per record (.0008).

There is no burden estimated for maintaining sale or distribution records under § 801.410(e) since firms are retaining their records as a normal and customary business practice for reasons of product liability.

Dated: November 20, 2000

Margaret M. Dotzel
Associate Commissioner for Policy

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